Legal Issues in 'Pharmaceutical-Trademarks & Marketing-Regulatory Approvals'

Issue: Whether Pharmaceutical Trademarks/Brand Names are regulated under the Drugs And Cosmetics Act, 1940

Primer on relevant concepts and sections under The Drugs And Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945

- The Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilisers play a major role in regulating the healthcare and pharmaceutical sectors. The agencies primarily responsible for regulating the import, manufacture, distribution and sale of drugs in India include:
  - **The Central Drug Standard Control Organisation (CDSCO)** - responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
  - **The State Drug Standard Control Organisations**; and
  - **The Drug Controller General of India (DCGI)**, established under the Drugs and Cosmetics Act 1940.

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- Further, the Drugs and Cosmetics Rules 1945 framed under the Drugs and Cosmetics Act sets down (among other things) the prescribed standards and procedural guidelines for its operation.

Primer on relevant concepts and sections under The Drugs And Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 (Contd.)

- The pharmaceutical industry notably accounts for the most trademark registration applications of any sector in India.
- Concept of look-alike sound-alike drugs (LASA) - LASA drugs are medications that look or sound similar to each other, either by their generic name, or brand name. They might have similar packaging, similar-sounding names, or similar spellings. Examples –
  - Celin (vitamin C) and Celib (non-steroidal anti-inflammatory medicine, which is used to relieve pain and inflammation);
  - Xyrof (helps relieve pain and reduces swelling, pain and redness in various joint conditions such as osteoarthritis and rheumatoid arthritis) and Zyrop 4000 (It is an injection that helps your bone marrow to produce more red blood cells. It is used to treat a type of anemia caused by kidney disease. It is also used to treat anemia caused by cancer chemotherapy and by taking medicines to treat HIV)
  - Tibitol (is an antibiotic that belongs to a class of medicines known as antituberculosis drugs) and Tobitil (is used in the treatment of Pain relief, Rheumatoid arthritis).

Primer on relevant concepts and Rules under The Drugs And Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 (Contd.)

- **Rule 96(1)(i)-A**:(1) Subject to the other provisions of these Rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely :—
  i. the name of the drug −
  [(A) for this purpose, the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name…

- **Section 17-B(e)**: Defines Spurious Drugs as under:

  "If it purports to be the product of a manufacturer of whom it is not truly a product."

  This provision not only prescribes protection against counterfeit drugs but also protect the "Brand Names" of the drugs."

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Primer on relevant concepts and rules under The Drugs And Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945 (Contd.)

- The Govt. of India u/s 33(P) of Drugs & Cosmetics Act, 1940 issued directions for grant/renewal of manufacturing licenses of Drug Formulations in Proper or Generic names only vide notice dated 01.10.2012 which made above mentioned provisions of Section 17-B(e) for spurious drugs, Rule 96(1)(i)-A and Rule 65-II-A redundant. Vide this order under Section 33-P, Govt. of India directed the State Govt. that –

"The grant of Drugs Manufacturing License under a Trade or Brand name is not in accordance to the spirit of legislation, therefore, Manufacturing License for drug formulations should be granted in Proper/Generic names only."

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now manufacturers were to apply and take Drug Formulation approvals only in Proper / Generic name without any Brand Name

Judiciary's approach with respect to LASA drugs

- In ***Allergan Inc. v. Milment Oftho*** [(1999 PTC (19) (DB) 160)] in the matter related to pharmaceutical eye care products of the parties, wherein names of both the products were identical *viz.* Ocuflox. A Division Bench (Ruma Pal and Devendra Kumar Jain, JJ.) of the High Court of Calcutta on the basis of trans-border reputation of the appellant and keeping in view the interest of the public, restrained the respondent from using the mark 'Ocuflox'. The Court observed that - "*To sum up: In the interest of the public there cannot be two medicinal preparations bearing the same name from different sources and with different compositions. One must go.*"

- In an earlier case of ***Astra-IDL Limited v. TTK Pharma Limited*** [AIR 1992 Bom 35] which dealt with the deceptive similarity of two marks, 'Betalong' and 'Betaloc' for pharmaceutical preparation, the defendant argued that since medicines could be sold by the chemists only on written prescription of a registered medical practitioner, there is no likelihood of confusion or deception by use of both the said marks. A Single Judge Bench (S.M. Jhunjhunuwala, J.) of the High Court of Bombay observed that - *"In my view, in the present circumstances, doctor's prescription factor has lost its importance since the reality of the situation cannot be ignored. In India scheduled drugs which are to be sold under doctor's prescription are even sold without production of doctor's prescription and as such reduces the weightage that can be given to this aspect of the matter while considering the question of deceptive similarity. The Court cannot close its eyes to the existing circumstances and judicial notice of the factual aspects in existence has to be taken."*

Judiciary's approach with respect to LASA drugs (Cont.)

- In the landmark judgement of ***Cadila Healthcare Limited v. Cadila Pharmaceuticals Limited*** [AIR 2001 SC 1952], a three Judge Bench (B.N. Kirpal, Doraiswamy Raju and Mr. Brijesh Kumar) of the Supreme Court of India in respect of similar drugs name in the pharmaceutical industry observed that *"Confusion between medicinal products may, therefore, be life threatening, not merely inconvenient. Noting the frailty of human nature and the pressures placed by society on doctors, there should be as many clear indicators as possible to distinguish two medicinal products from each other."*

  The Supreme Court further observed that *"Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which inter alia indicates that an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark Office pertaining to the trade mark in question which will enable the Drug Authority to arrive at a correct conclusion."*

Judiciary's approach with respect to LASA drugs (Cont.)

- Recently in the case of ***Curewell Drugs and Pharmaceuticals Pvt. Ltd. and Ors. v. Ridley Life Science Private Limited and Ors.*** [2019 (77) PTC 657 (Del)] a Single Judge Bench (Prathiba M. Singh, J.) of the High Court of Delhi held that *"The issue of pharmaceutical preparations and medicines being sold under identical brand names has been a concern in a large number of disputes. The said issue is not just one which concerns statutory rights or trademark rights of a particular IP owner, but has a larger impact on the health of the patients. Stringent quality control mechanisms ought to be put in place and implemented in the manufacture and sale of medicines. If medicines are allowed to be sold with identical brand names and that too in identical packaging, it is not just violative of the rights of IP owners but dangerous for consuming patients"*. The High Court of Delhi further asked the DCGI and the state drug regulators to implement an action plan in which drugs with identical or near-identical brand names or marks are not given licences to ward off confusions.

Plaintiff's Packaging

Defendant's packaging

Recent amendment to the Drugs and Cosmetics Rules, 1945

- Soon after the *Curewell* judgement, the Central Government issued a notification dated November 6, 2019 in official gazette amending the Drugs and Cosmetics Rules, 1945. The amendment reads as under–

- *2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules), in rule 71, after subrule (8), the following sub-rule shall be inserted, namely:— "(9) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.".*

Recent amendment to the Drugs and Cosmetics Rules, 1945 (Contd.)

7. In the said rules, in Schedule A, after Form 50, the following Form shall be inserted, namely:—

"FORM 51

[See rules *71(9), 71A(5), 71B(v), 76(11) and 76A(v)]*

Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name

(1) I ..... of..... intend to market the drug specified below under a brand name or trade name - .....

(i) Name of the drug :

(ii) Dosage form :

(iii) Composition :

(2) I hereby give this undertaking that to the best of my knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

Place.....

Date .....

[Signature, Name, Designation Seal/Stamp of manufacturer or on behalf of the manufacturer].".

[F. No. X.11018/48/2018-DRS]

Recent reported cases of similar brand names of pharma goods

- ***Arudra Engineers Private Limited and Ors. v. Patanjali Ayurved Limited and Ors.***, (O.S.A. No. 169 of 2020 and C.M.P. Nos. 8510, 9187 and 9188 of 2020) - One such example is the recent trademark application by Patanjali for registering the mark Coronil under Class 5, against which an infringement suit is filed by one M/s. Arudra Engineers Pvt. Ltd, claiming the mark to be similar to their registered mark "Coronil-213 SPL" and "Coronil-92B". Since M/s. Arudra Engineers Pvt. Ltd, have been registered user of the mark since 1993, hence an interim order restraining Patanjali from selling the product under the name Coronil was granted. However, the bigger question in issue is how the manufacturing license of a drug under the Drugs and Cosmetic Act is granted without verifying the registration of the Trademark

- ***Sun Pharmaceutical Industries Ltd. v. Cipla Limited***, (Apln Nos.1980, 1982 and 1983 of 2021 and 1949 of 2021) - The plaintiff, Cipla, established that it has an established consumer base for the medical products 'Budecort Respules' and 'Duolin Respules' which are products of the salts Budeonide Nebuliser Suspension BP and, Levosalbutamol and Ipratropium Bromide Respirator Solution. They submitted that the mark 'Respules' was coined and has been registered and used since 2013. These medicines were sold by the plaintiff in a unique and colourful packaging.

THANK YOU!

Questions?

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